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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/337,675	06/22/1999	RAJEEV A. JAIN	029318/0497	9275

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
02/18/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/337,675	JAIN ET AL.	
	Examiner	Art Unit	
	S. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-22 and 25-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-22 and 25-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :05/23/08;09/10/08;12/12/08;01/09/09;02/17/09;and 03/24/09.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 4-11, 13-22, 25-38, 41-43, 45, 46, 49, 50 and 53 are rejected under 35 U.S.C. 102(a) as being anticipated by Liversidge et al. WO 99/02665 A1.

Liversidge teaches a solid dosage form comprising: 1) nanoparticulate drug having effective average particle size less than about 1000 nm, preferably less than 400 nm; and 2) cellulosic surface stabilizer adsorbed on the surface thereof (page 5, paragraphs 2-6; and page 12, paragraphs 2-3). The nanoparticulate further comprises additional surfactants (pages 10-11). The solid dosage form further comprises binder, filler, lubricant, disintegrant, and other excipients (page 7, paragraphs 2-3). Liversidge further teaches a process for preparing the solid dosage form (page 16, last paragraph through page 19).

It is noted that Liversidge does not teach the functional limitation of the claims, such that the nanoparticulate composition provides controlled release of the nanoparticulate drug for a time period ranging from about 2 to about 24 hours. However, such limitation is inherent because Liversidge teaches the same solid composition comprising poorly soluble nanoparticulate drug having the claimed effective average particle size, because Liversidge teaches the use of the same surface

stabilizer, and the same high molecular weight polymer in the claimed concentration. Surface stabilizer includes gelatin, casein, lecithin, gum acacia, cholesterol, tragacanth, stearic acid, and the like (page 10). Cellulosic surface stabilizer (high molecular weight polymer) includes hydroxypropylmethyl cellulose (HPMC) in an amount ranges from about 0.1% to about 90% (page 10, 2nd paragraph; and page 11, last paragraph through page 12, lines 1-3). It is noted that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

Claim Rejections - 35 USC § 103

Claims 1, 4-10, 12-18, 21, 22, 25, 26, 30, 32-35 and 37-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doi et al. US 4,665,081, in view of Sugimoto et al. US 4,765,990.

Doi teaches a solid nifedipine preparation comprises a particulate dry composition of nifedipine, casein (surfactant), one or more inorganic excipient, an enteric high molecular substance, and a plasticizer (abstract; and column 5, lines 56-66). Enteric high molecular substance includes cellulose acetate phthalate, HPMC phthalate, methyl methacrylate copolymer, polyvinyl acetate phthalate, cellulose acetate succinate, and styrene-maleic acid copolymer (column 6, lines 15-22). Plasticizer includes polyethylene glycol (column 6, lines 23-29). Enteric high molecular substance

is in an amount of about 70% (Table 1). The solid preparation further comprises binder, lubricant, and the like excipients (column 8, lines 1-11). Doi further teaches a process for preparing the solid preparation (column 7, lines 20 through column 8, lines 1-48).

Doi does not teach the particle size of nifedipine.

Sugimoto teaches a novel preparation of nifedipine comprising fine powder nifedipine having average particle size of not more than 5 μ; a nontoxic hardly water-soluble substance and an enteric high molecular compound coated on the surface of the nifedipine fine powder (column 1, lines 60-65). Thus, it would have been obvious to one of ordinary skill in the art to optimize the solid nifedipine preparation of Doi using fine powder nifedipine having the claimed average particle size. This is Doi teaches the desirability for using finely divided nifedipine granule, and because Sugimoto teaches the use of fine granule nifedipine having an average particle size preferably about 1 μ for a solid preparation is useful in pharmaceutical art (column 3, lines 6-9).

Doi further does not teach the release period ranging from about 2 to about 24 hours. However, the burden is shifted to applicant to show that the controlled release nifedipine solid dosage of Doi does not exhibit a release rate ranging from about 2 hours to 24 hours. This is because Doi teaches the use of the same rate controlling high molecular weight polymer in the claimed amount to obtain a solid nifedipine dosage form having controlled release characteristic (column 8, lines 49-56).

Response to Arguments

Applicant's arguments filed 03/25/08 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615